71. A topical composition of matter for preventing in a mammal a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises (a) a prophylactically phagocytosis- or ICAM-1-decreasing effective amount of an agent that specifically decreases phagocytosis or ICAM-1 expression, and (b) a pharmaceutically or cosmetically acceptable carrier.

72. A method of decreasing phagocytosis or ICAM-1 expression in a mammalian cell, comprising topically contacting the cell with a phagocytosis- or ICAM-1-decreasing effective amount of an agent that specifically decreases phagocytosis or ICAM-1 expression.

73. A method according to claim 72 wherein said agent comprises a serine protease inhibitor.

74. A method according to claim 72 wherein said agent comprises a soybean derivative. soybean milk.

REMARKS

This Amendment is respectfully submitted in response to the Office Action dated March 22, 2001. The application has been amended as follows: new claims 70-74 have been added. Such amendments find support in the Specification as follows: in original claims 2, 4, 24 and 29 and page 20, l. 1-20.

The Office Action of March 22, 2001 acknowledged the provisional election of the claims of Group II, i.e., claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 and the election of species of soybean derivative, keratinocytes and skin disorders.

Claims 2, 4, 8-21, 24, 28-35, 38, 40 and 44-47 were rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. The basis on which this rejection was made is as follows:

> The elected species of the claims reads on soybean milk used to treat skin disorders. The reference teaches that soybean milk can be used to treat a tumor on mouse skin. [Office Action, p. 3]

The Office Action of March 22, 2001 also rejected claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102(b) as being anticipated by Hagiwara et al., Kosaka, JP 6236304, JP 408143442A or JP 08143442A on the ground that each reference teaches using soybean milk to treat skin disorders.

Claims 2, 4, 8-22, 24, 38-46, 48, 50, 55-57 and 58 were further rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with Kosaka, JP 62036304, JP 408143442A or JP 08143442A. The basis for this rejection was that:

> Limtrakul teaches using soybean milk to treat a skin disorder, namely a tumor growing on the skin...The reference does not teach using the soybean milk on a human...The secondary references each teach using soybean milk on human skin to treat a skin disorder...Thus, it would have been obvious to one of ordinary skill in the art to treat a human with the composition of Limtrakul when Limtrakul was taken with the secondary references which teach that human skin can be treated with soybean milk to treat skin disorders. [Office Action, p. 6]

Applicants respectfully request reconsideration of the foregoing rejections under 35 U.S.C. 102 and 103 in view of the ensuing discussion.

Limkatrul et al. relates to the effect of soybean milk protein in a two-stage carcinogenesis experiment on mouse skin. Soybean milk protein was given orally to mice to which a tumor initiator and a tumor promoter were applied. Limkatrul et al. found that the number and volume of tumors were lower in the group of mice who ingested soybean milk protein than in the comparison group. [Limkatrul et al., p. 1] As recognized by the Office Action, nowhere does Limkatrul et al. suggest or disclose the administration of soybean milk to humans. Furthermore, Limkatrul et al. recognizes that "...There have been reports on the unfavorable effects of soybean trypsin inhibitor for health." [Limkatrul, et al, p. 1592] Nowhere does Limkatrul et al. suggest or disclose the application of soybean milk protein topically. maybe 103

Limkatrul et al. teaches that soybean trypsin inhibitor (STI) is unfavorable for health, thus teaching away from the use of such compounds in mammals. STI compounds are destroyed by processing soybean derivatives, such as by heating. This process eliminates microbial contamination, and inactivates STI compounds. If STI compounds are not inactivated, oral consumption results in diarrhea, a contraindication. The compositions of applicants' invention require that the STI components of the soymilk be active in order to affect phagocytosis. Furthermore, Limkatrul describes the effect of dietary soymilk in a two-stage carcinogenesis study and its effect on skin tumors. Nowhere does Limkatrul suggest or describe the topical use of soymilk nor does it suggest or disclose the use of topically-applied soymilk to affect phagocytosis.

* see p. 1592 of ref.
* where is this? p. 1591 *

The other cited references do not remedy the deficiencies of Limkatrul et al. in rendering the compositions and methods of applicants' invention anticipated or obvious.

Hagiwara et al. relates to a process for preparing food products containing a lactic acid bacteria-fermented product of a cereal germ. The product of Hagiwara et al. is a fermented product, which is cultivated in a hot-water extraction of cereal germ. Such hot water extraction and fermentation tends to denature and inactivate STI compounds. Furthermore, nowhere does Hagiwara et al. suggest or disclose the methods or compositions of applicants' invention in that nowhere does it mention the use of soymilk to affect phagocytosis.

Applicant elected Soybean milk

Nor does the Kosaka reference mention or disclose the compositions or methods of applicants' invention. Kosaka relates to medicinal compositions, foods and beverages having therapeutic effects on certain specific diseases of the circulatory and digestive systems. Kosaka also requires the addition of papain and citric acid administered orally. Papain is an enzyme characterized as a serine protease; in contrast, the compositions of applicants' invention contain serine protease inhibitors. Moreover, Kosaka does not disclose or suggest topical compositions or methods for their application or use in affecting phagocytosis.

applicant elected Soybean milk.

While JP 62036304A, JP 08143442A and JP 408143442A refer to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere do they suggest or describe the use of non-denatured soy products for increasing or decreasing phagocytosis. JP 08143442A uses the term "soybean milk", however, it describes compositions that are different from those set forth in applicants' claims. JP 08143442A describes compositions that are either (1) supernatants or aqueous extracts of soybeans or (2) heated, filtered, evaporated soybean milk for the treatment of "coarse skin". In contrast, the compositions of applicants' invention should not be subjected to heat, as it denatures and inactivates the active STI components of applicants' compositions. Furthermore, nowhere does JP 08143442A suggest or disclose the methods of using the compositions of applicants' invention to affect phagocytosis.

Inherent

How different?

applicant didn't elect STI

SO!?!

JP 62-3336304A merely refers to the use of soybean milk as a cosmetic for skin and hair or for "conditioning". Nowhere does it recognize the necessity of maintaining the presence of nondenatured STI components in soymilk compositions nor does it recognize

STI not elected

or disclose the use of soymilk containing nondenatured STI components for affecting phagocytosis.

JP 408143442A mentions an external preparation for preventing "chapped skin, hand eczema, sore and itching caused by dermatophytosis, blended with an extracted solution of soybeans with water." [JP 408143442A, p. 1]. It does not describe the compositions of applicants' invention in that the preparation is the aqueous supernatant of soybeans that are treated by subjecting them to conditions that range from 5-100° C for 5 minutes to 20 hours—those preparations resulting from processing at the lower end of the range probably do not contain much, if any, active ingredient, and those resulting from processing at the higher end of the range have had the STI components inactivated or denatured. The compositions of applicants' invention contain the beans themselves, which contain active STI components. JP 408143442A does not recognize the importance of maintaining the activity of such components nor does it disclose or suggest the claimed compositions and methods. Furthermore, nowhere does this abstract mention or suggest the use of soymilk compositions for affecting phagocytosis.

not what applicant claimed.

Thus, none of the cited references, taken alone or together, specifically disclose the use of compositions containing phagocytosis- or ICAM-1-affecting components for the method of affecting phagocytosis or ICAM-1 expression. None of the references recognizes the importance of maintaining the integrity of STI components in soymilk; none even mentions phagocytosis or ICAM-1 expression. In view of the foregoing discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of March 22, 2001 under 35 U.S.C. 102 and 103.

The Office Action provisionally rejected claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 on the ground that that application "discloses the composition of soybean milk and a cosmetically acceptable carrier/vehicle and discloses a method of using the composition which inherently will decrease phagocytosis or ICAM-1 expression in a mammalian cell as in the instant application." [Office Action, p. 4] Applicants respectfully requests reconsideration of this rejection in view of the ensuing discussion.

Although both applications relate to compositions containing soybean milk, the methods of use are different and not necessarily inherent. Furthermore, both applications have certain common inventors, including Dr. Miri Seiberg, Dr. Stanley Shapiro, Dr. Susan

Niemiec and Mr. John Kung. The applications are co-assigned to Johnson & Johnson Consumer Companies, Inc. As this rejection is provisional, applicants will make submissions under 37 C.F.R. 1.131 or 1.132 as appropriate once claims are allowed in either the instant application or Serial No. 09/110,409.

The Office Action provisionally rejected claims 2, 4 and 8-22 under 35 U.S.C. 101 as claiming the same invention as that of claim 60 of copending patent application Serial No. 09/110,409 on the ground that the claims of the instant application and claim 60 of 09/110,409 are directed to the same composition and a cosmetically acceptable vehicle/carrier. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 were also provisionally rejected under the judicially created doctrine of double patenting over claims 1-60 of copending patent application Serial No. 09/110,409. Applicants respectfully submit that the subject matter set forth in the instant application and that disclosed and claimed in Serial No. 09/110,409 are not coextensive nor that the subject matter of the instant application is taught in Serial 09/110,409. Notwithstanding, should this rejection be confirmed, Applicants will address it once claims are allowed in either the instant application or Serial No. 09/110,409.

In view of the foregoing amendments to the claims and discussion, applicants respectfully request reconsideration of the rejections set forth in the Office Action of March 22, 2001. An early allowance is earnestly solicited.

Respectfully submitted,

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